

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS AG,
NOVARTIS PHARMA AG, NOVARTIS
INTERNATIONAL PHARMACEUTICAL
LTD. and LTS LOHMANN THERAPIE-
SYSTEME AG

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC.

Defendant.

C.A. No. 11-1077-RGA
C.A. No. 13-1467-RGA

**PAR PHARMACEUTICAL, INC.'S
NOTICE OF SUBSEQUENT AUTHORITY IN
SUPPORT OF ITS POST-TRIAL BRIEFING ON INVALIDITY**

Pursuant to D. Del. LR 7.1.2(b), Defendant Par Pharmaceutical, Inc. (“Par”) hereby submits this Notice of Subsequent Authority in support of its Post-Trial Briefing on Invalidity (D.I. 401 and 418 in Case No. 11-1077-RGA), due to the recent issuance of a decision by the U.S. Court of Appeals for the Federal Circuit in *AbbVie Deutschland GmbH & Co., KG. v. Janssen Biotech, Inc.*, __ F.3d __, 2014 WL 2937477 (Fed. Cir. July 1, 2014) (attached as Exhibit A), regarding written description under 35 U.S.C. § 112. The parties completed their post-trial briefing on invalidity on June 20, 2014.

In its Post-Trial Briefing on Invalidity (D.I. 401 and 418), Par asserted that if acetaldehyde were determined to be an antioxidant based on Plaintiffs’ infringement evidence presented at trial, then the patent-in-suit, U.S. Patent No. 6,335,031 (“the ’031 patent”), is invalid for lack of written description because the patentees were not in possession of the invention as

broadly claimed, *i.e.*, rivastigmine transdermal patches stabilized using any compound that might reduce oxidative degradation of another compound, by any amount, in any of an unlimited number of potential tests—such as acetaldehyde, which was not described or recognized in the '031 patent as an antioxidant.

In *AbbVie*, the Federal Circuit stated that “[f]unctionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus.” Slip. Op. at 26. Plaintiffs are asserting an overbroad functional scope for “antioxidant,” which would improperly require the public to predict what compounds fall within the “antioxidant” genus, with no defined standard for making that determination.

Moreover, the Federal Circuit noted that in order to meet the written description requirement, the patents-in-suit need not describe an allegedly infringing product in exact terms, but “must at least describe some species representative of antibodies that are structurally similar to” the accused product. *Id.* at 25. The Federal Circuit concluded that the asserted claims were invalid for lack of written description because “there is no evidence to show any described antibody to be structurally similar to, and thus representative of [the accused product]. There is also no evidence to show whether one of skill in the art could make predictable changes to the described antibodies to arrive at other types of antibodies such as [the accused product].” *Id.*

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/s/ Steven J. Fineman

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